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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-846,634	05.01.2001	Ick-Dong Yoo	1728/1F088-US1	5673

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DARBY & DARBY P.C.
805 Third Avenue
New York, NY 10022

EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1651	6

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/846,634	Applicant(s) Ick-Dong Yoo et al.
	Examiner Vera Afremova	Art Unit 1651
		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Jul 6, 2001
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4 and 5 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4 and 5 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-4131 Paper No(s) _____)
16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO 948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO 152)
17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO 1449) Paper No(s) _____	20) <input type="checkbox"/> Other _____

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DETAILED ACTION

Claims 4 and 8 are pending and under examination.

Claims 1-3 and 5-7 were canceled by applicants in the Paper No. 2 filed 5/01/2001.

Specification

The disclosure is objected to because of the following informalities: The address of the Korean Collection for Type Cultures (KCTC) is missing (see page 6, for example).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Deposit

Claims 4 and 8 are rejected under 35 U.S.C. 112, first *paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism *Phellinus linteus* KCTC 0399BP. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

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The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a **statement** by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37CFR 1.808.

Because Korean Collection for Type Cultures (KCTC) has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection.

Indefinite

Claims 4 and 8 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rendered indefinite by parentheses because the use of parentheses encompassing terminology in the claims is unclear whether or not what is stated in parentheses is a further limitation or simply alternative meaning. It is suggested to remove parentheses.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. [U] taken with US 4,051,314 [IDS-1], US 4,877,777 [A] and KR 97-15743 [N].

Claim 4 is directed to a method for preparing a polysaccharide substance with immunostimulating activity wherein the method comprises step of culturing a fungal culture belonging to *Phellinus linteus* on media containing glucose, yeast extract and peptone to obtain mycelia; step of extracting the substance from the mycelia by hot water; step of isolating the substance by precipitation in ethanol, suspending in water and by dialysis and step of purifying the substance by using DEAE-cellulose chromatography and gel-chromatography. Claim 9 is further drawn to a polysaccharide obtained by the claimed method wherein polysaccharide comprises glucose units joined by α (1-4) and β (1-6) linkages.

Lee et al. [U] disclose a fungal polysaccharide substance with immunostimulating activity and a method for preparing the polysaccharide substance wherein the method comprises step of culturing a fungal strain L13202 belonging to the fungal species of *Phellinus linteus* (page 326, col. 1, last three lines) on media containing glucose, yeast extract and peptone (table 1, page 326) to obtain fungal mycelia; step of extracting the substance from the fungal mycelia with hot water

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(page 326, col. 2, last paragraph); step of isolating and purifying the substance by precipitation in ethanol, suspending in water and dialysis (page 327-, col.1, lines 11-15). The cited reference teaches that polysaccharide substances derived from fungal cultures or mushrooms are characterized by immuno-stimulating activity or anti-tumor activity and that the fungal polysaccharide comprise glucose units and $\beta(1\rightarrow 6)$ linked branches (page 325, col. 1). The cited reference is lacking particular disclosure related to purification steps such as the use of DEAE-cellulose chromatography and gel chromatography in a method for preparing a fungal polysaccharide substance from a fungal strain belonging to *Phellinus linteus*.

However, US 4,051,314 [IDS-1] teaches that the fungal polysaccharide substances with immuno-stimulating activity or anticarcinogenic activity (abstract) are prepared from fungal cultures including cultures belonging to *Phellinus sp.* (see col. 6, example 1 or col. 22, example 18) wherein the methods of preparation of fungal polysaccharides encompass the use of hot water extraction, precipitation in ethanol, suspending in water, dialysis as well as the use of purification procedures such as application of cellulose chromatography (col. 7, lines 12-40) and gel-chromatography or filtration (col.3, line 36-40).

In addition, KR 97-15743 [N] teaches that an anticancer immunoactive polysaccharide substance derived from a fungal culture belonging to *Phellinus linteus* (see English title) strain KCTC 0173BP (see fig. 1) is prepared and purified by using DEAE-cellulose chromatography (see fig. 1).

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US 4,877,777 [A] is relied upon for the teaching that the fungal polysaccharide substances which are characterized by immunobiological responses (col. 2, line 59) comprise glucose units joined by α (1-4) and β (1-6) linkages (col. 2, lines 33-35 and col. 28, example 8).

In view of the teachings of the cited references, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the method for preparing polysaccharide substance derived from *Phellinus linteus* disclosed by Lee et al. [U] by applying purification steps including cellulose chromatography and gel-chromatography as taught by US 4,051,314 [IDS-1] and by KR 97-15743 [N] with a reasonable expectation of success in obtaining polysaccharide substances with immunostimulating effects because similar, if not identical, polysaccharides have been prepared and purified from fungal cultures belonging to *Phellinus sp.* {US 4,051,314 [IDS-1]} including *Phellinus linteus* {KR 97-15743 [N]} and because it is known that fungal polysaccharide substances with immunostimulating effects comprise glucose units joined by α (1-4) and β (1-6) linkages {US 4,877,777 [A]}. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. It is noted that applicants conducted an extensive research for taxonomical identification and/or classification of the fungal strains belonging to *Phellinus linteus* including several ATCC strains. However, it is uncertain what characteristics of the claimed strain KCTC 0399BP are intended by applicants as "novel" features (page 6, last line). It is also uncertain what are the differences between the claimed strain KCTC 0399BP and the other fungal strains including PL5, for example, which appears to be identical to KCTC 0399BP as disclosed

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(FIG. 1) and what are the difference between the prior art fungal strains/polysaccharides and the applicants' fungal strains capable to produce polysaccharide substances of interest.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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March 6, 2002.

Irene Marx
IRENE MARX
PRIMARY EXAMINER